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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/710,423	07/09/2004	Richard Heller	1372.32.UTLCPDV2	5054

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EXAMINER	
WITCZAK, CATHERINE	
ART UNIT	PAPER NUMBER
3767	
MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/710,423	HELLER ET AL.	
	Examiner	Art Unit	
	Catherine N. Witczak	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

9/26/07

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/20/2007 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 8, & 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver (US Patent No. 5389069) in view of Eggers et al (US Patent No. 5681282). The Weaver reference discloses a device for manipulating a molecule in vivo relative to a target tissue in figure 5 comprising an elongated member 148 comprising a generally cylindrical nonconductive core post and at least two discrete electrodes (152,154); the least two discrete electrodes being circumferential rings disposed about the core and in axially spaced relation along the elongated member, each electrode being in circuit communication with a respective portion of a source of electrical energy, the discrete electrodes being configured to establish a first electromagnetic field in vivo between selected electrodes sufficient to cause an electromigration of a molecule relative to a target tissue and a second electromagnetic field sufficient to cause a transient permeability of

a cell membrane within the target tissue; and an insulating material (seen as the material between the two electrodes) interposed axially between the electrodes for achieving relative electromagnetic isolation of the electrodes, also see col. 2 lines 8-60 & col. 8 lines 5-21. Now even though Weaver does not explicitly disclose more than two electrodes or the electrodes to be independently in communication with a power source attention is directed to Eggers. The Eggers reference teaches an electrosurgical device that utilizes multiple electrodes that can all be independently controlled and connected to a power source, see col. 5 lines 11-22 & col. 5 line 66 - col. 6 line 15. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Weaver with the teachings of Eggers in order to provide an apparatus that can be utilized over a larger area and can selectively apply energy to the patient while limiting unwanted heating.

With respect to claim 2, wherein the second field can be stronger than the first field when the first field is not activated by the independently controlled circuit.

With respect to claim 3-4, the tip seen as the distal end of part 148 in figure 5.

With respect to claim 8, wherein the device is fully capable of having the electrodes substantially simultaneously activatable due to it's size, shape, and ability to work in the environment.

Claims 1-4, 8, & 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al (US Patent No. 5941845) and further in view of Eggers et al (US Patent No. 5681282). The Tu reference discloses a device for manipulating a molecule in vivo relative to a target tissue comprising an elongated member comprising a generally cylindrical nonconductive core post and at least two discrete electrodes; the least two discrete electrodes being circumferential rings disposed about the core and in axially spaced relation along the elongated member, each electrode

being in circuit communication with a respective portion of a source of electrical energy, the discrete electrodes being configured to establish a first electromagnetic field in vivo between selected electrodes sufficient to cause an electromigration of a molecule relative to a target tissue and a second electromagnetic field sufficient to cause a transient permeability of a cell membrane within the target tissue. Now even though Tu does not explicitly disclose more than two electrodes or the electrodes to be independently in communication with a power source or insulating material between the electrodes attention is directed to Eggers. The Eggers reference teaches an electrosurgical device that utilizes multiple electrodes that can all be independently controlled and connected to a power source as well as insulation between the electrodes for achieving relative electromagnetic isolation of the electrodes, see col. 5 lines 11-22 & col. 5 line 66 - col. 6 line 15. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Weaver with the teachings of Eggers in order to provide an apparatus that can be utilized over a larger area and can selectively apply energy to the patient while limiting unwanted heating as well as to isolate the electrodes in order to prevent interruptions in flow.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver (US Patent No. 5389069) in view of Eggers et al (US Patent No. 5681282) or Tu et al (US patent No. 5941845) in view of Eggers et al (US Patent No. 5681282) as applied to claim 1 and further in view of Hofmann et al (US Patent No. 6233482B1). Now even though Weaver or Tu does not explicitly disclose a plurality of members configurable to surround a periphery of a tissue or provide opposite-polarity voltages or active a plurality of electrodes in a predetermined pattern, attention is directed to Hofmann..The Hofmann reference teaches the use of a plurality of electroporation members to surround tissues, utilize opposite-polarity voltages, and activate electrodes in a predetermined pattern, see figures 2A-G, 6, & 7A-D, col. 3 line 62 - col. 8 line 36.

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Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Weaver or Tu with the teachings of Hofmann in order to provide electroporation therapy to a larger area as well as customizing the therapy to different tissues and operations.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver (US Patent No. 5389069) in view of Eggers et al (US Patent No. 5681282) or Tu et al (US patent No. 5941845) in view of Eggers et al (US Patent No. 5681282) as applied to claim 1 and further in view of Edwards et al (US Patent No. 5472441). Now even though Weaver or Tu et al does not explicitly disclose the member having a lumen and a portal, positioned along the member or adjacent a bottom tip or adjacent an electrode, for passing a substance therethrough to the target tissue attention is directed to Edwards. The Edwards et al reference teaches the use of a lumen through an electroporation member for fluid distribution for treatment.of the tissues with an agent. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Tu to utilize the teachings of Edwards in order to help facilitate the distribution of the fluid treatment agents.

Response to Arguments

Applicant's arguments filed 7/20/2007 have been fully considered but they are not persuasive. Applicant admits on the last line of page 5 of the arguments that "Egger describes establishing an electromagnetic filed between one individual electrode and a common electrode." As such, Examiner maintains that the Egger reference does disclose "discrete electrodes being configured to establish a first electromagnetic field in vivo between selected electrodes," as the common electrode and the individual electrodes of the Egger reference are each "discrete" electrodes.

Conclusion

All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cw

9/28/06

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER